

REMARKS

The present application relates to inbred maize line PH7JD. Claims 3, 4, 5, 9, 11, 12, 14, 21, 22, 23, 24, 28, 30, 40, 41, 42, 43, and 47 have been amended. New claims 50-73 have been added. Claims 17-20, 31-33, 36, and 44-46 have been canceled. No new matter has been added by the present amendment. Applicants respectfully requests consideration of the following remarks.

Detailed Action

A. Claim and Specification Objections

Applicants acknowledge the objection to claims 8 and 27 as withdrawn. Applicants further acknowledge the rejection of claims 1-49 under the judicially created doctrine of obviousness-type double patenting is withdrawn. The rejection of claims 1-49 under 35 U.S.C. § 112, second paragraph are acknowledged as withdrawn in light of the previous claim amendments. Applicants also acknowledge the rejection of claims 1-49 under 35 U.S.C. § 112, first paragraph as withdrawn, in light of the deposit.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 3, 5, 12, 13, 22, 24, 30-33, 40-44, and 47-49 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention.

Claims 3 and 22 stand indefinite for the recitation "wherein said plant has been manipulated to be male sterile."

Applicants have now amended claims 3 and 22 to delete the language "manipulated to be male sterile", thus alleviating this rejection.

The Examiner rejects claims 5 and 24 for improper antecedent basis for "protoplasts" in line 1.

Applicants have now amended claim 4 which claim 5 depends thereon and claim 23 which claim 24 depends thereon to include --regenerable cells or protoplasts--, thereby providing proper antecedent basis and alleviating the rejection to claims 5 and 24.

Claims 12, 31, and 40 are indefinite for the recitation "comprising" in line 1 which the Examiner states does not clearly indicate how many crosses are to be performed by the method.

Applicants have now amended claims 12 and 40 to include the language --F1 hybrid--, as suggested by the Examiner, alleviating this rejection. Further, claim 31 has been canceled.

The Examiner rejects claims 30 and 47 as indefinite for the recitation "essentially unchanged".

Applicants have amended claims 30 and 47 to delete the terminology "essentially unchanged", thus alleviating this rejection.

Claim 33 stands rejected as unclear what is meant by a pedigree being within 2 or less crosses to a plant other than PH7JD.

Applicants have canceled claim 33, thereby alleviating this rejection.

In light of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 9-14, 17-20, 28-33, 36-39, 41-44, 47-79 remain rejected and claims 15, 16, 34, 35, and 40 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office Action mailed July 30, 2002.

The Applicants traverse the rejection. Claims 17-20, 31-33, 36, and 43-46 have been canceled. Claims 3, 4, 5, 9, 11, 12, 14, 21, 22, 23, 24, 28, 30, 40, 41, 42, and 47 have been amended. New claims 50-73 have been added.

The Examiner rejects claims 9, 10, 28, and 29, that claim the F1 hybrid seed and F1 hybrid plant made with PH7JD as a parent. Claims 9 and 28 have been amended and claims 10 and 29 refer directly to claims 9 and 28. One of ordinary skill in the art would know how to cross PH7JD with another maize plant. Applicants assert it is well

understood by one skilled in the art that maize is a diploid plant species thereby comprising two sets of chromosomes. The F1 hybrid seed and plant produced using PH7JD, regardless of the other maize plant used, is identifiable because it will have a single set of individual maize chromosomes coming from PH7JD. Therefore, it would be clear to one ordinarily skilled in the art that the addition of claim terminology --having a single set of maize chromosomes from PH7JD-- in claims 9 and 28 would certainly be understood. In addition, one of ordinary skill in the art would be able to run a molecular profile on PH7JD and the F1 hybrid and be able to identify the F1 hybrid as being produced from PH7JD. Claims 9 and 28 have now been amended to specify that the resulting F1 hybrid must have one set of maize chromosomes from PH7JD. PH7JD is an inbred plant which is homozygous at every locus, and thus contains two sets of the same chromosomes. When the ovule or pollen are generated from this plant, it will be haploid and will contain one complete set of chromosomes from PH7JD. Upon fertilization, the resulting zygote will receive one set of chromosomes from the parent inbred plant resulting in the diploid zygote. Inbred PH7JD has a unique set of genes present on its chromosomes and this unique set is also present in the hybrid.

As stated in the specification on page 16, lines 9-34, there are many laboratory-based techniques available for the analysis comparison and characterization of plant genotype such as Restriction Length Polymorphisms (RFLPs) and Simple Sequence Repeats (SSRs). Such techniques may be used to identify whether or not PH7JD was used to develop a hybrid. Any person of skill in the art could run a molecular profile of PH7JD based upon the deposit Applicants have made. Therefore, it would be routine to one of ordinary skill in the art to run the profile of a hybrid plant and determine whether or not PH7JD was used as a parent.

Claim 17 has also been canceled. Claim 14 has been amended providing one of skilled in the art sufficient description to evaluate the presence of the claimed traits. Claims 15 and 16 remain pending and are to methods of making a maize plant through the utilization of PH7JD. Applicants point out that anyone of skill in the art would know how to utilize the well established breeding methods with PH7JD. Description of such occurs throughout the specification and descriptions can also be found in introductory plant breeding books. As stated in the written description guidelines, an old process

performed with a novel material is novel in and of itself. 66 Federal Register 1099, Vol. 66, No. 4 (January 5, 2001). Further, claims 15 and 16 are methods patentable pursuant to the written description guidelines. See Example 10, Revised Interim Written Description Guidelines Training Materials.

Claim 40 has been amended. Claim 40 is to the method of producing a first generation (F1) PH7JD-progeny maize plant. Claim 41 is to the first generation (F1) PH7JD-progeny maize plant produced by the method of claim 40. The first generation (F1), or hybrid, is identifiable through both breeding records and molecular marker techniques as discussed above. Further as described herein, claim 41 requires that the hybrid have the complete set of PH7JD maize chromosomes which are present in duplicate form in the inbred parent. Claim 42 is to the method of selfing the first generation (F1) PH7JD for successive filial generations. Claim 43 is to the PH7JD-derived maize plant produced by the method of claim 42. Applicants assert claim 43 is a method patentable pursuant to the written description guidelines. See Example 10, Revised Interim Written Description Guidelines Training Materials. This is a basic and well known breeding methodology, and the use of this methodology with PH7JD is described in the specification on page 21, lines 16 to 31.

As stated in Openshaw et al. submitted herewith, "[t]he backcross breeding procedure has been used widely to transfer simply inherited traits into elite genotypes. ... Today, backcrossing is being used to transfer genes introduced by such techniques as transformation or mutation into appropriate germplasm." Openshaw et al. further notes breeders, by using molecular markers, may obtain 98% and greater genome identity between the backcross conversion and the recurrent parent after two backcrosses. See Marker-assisted Selection in Backcross Breeding, Openshaw, S.J. et al. Marker-assisted selection in backcross breeding. In: Proceedings Symposium of the Analysis of Molecular Data, August 1994, pages 41-43. Crop Science Society of America, Corvallis, OR (1994) included as Appendix A. The backcross method has been successfully used since the 1950's (see pages 585-586 of Wych, 1988 included in the Information Disclosure Statement). Thus Applicants assert such mutant genes or transgenes may be introgressed into elite lines such as PH7JD without undue experimentation. As further evidence of this, Poehlman et al. (1995) on page 334, submitted in the Information

Disclosure Statement, states that, "[a] backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross." In addition, Wych (1988) on page 585-86, discusses how the male sterility trait is routinely backcrossed into an inbred line and how this is used to produce a sterile/fertile blend of an F1 hybrid in order to reduce seed production costs. In fact, many commercial products are produced in this manner, and those of ordinary skill in the art consider the F1 hybrid produced with the male sterile (backcross conversion) inbred to be the same variety as the F1 hybrid produced with the non-backcross conversion inbred.

The Examiner states that "the molecular profile of PH7JD is not described in the specification." Applicants respectfully traverse this rejection. As described in the specification, lines 9-34 on page 16, the seed deposit allows one of ordinary skill to run a molecular profile of PH7JD. Thus, one of ordinary skill in the art may test material they desire to use in breeding to determine if it is PH7JD. An SSR profile is an inherent feature of inbred line PH7JD, a representative sample of which has been deposited with the ATCC. For example, see Ex parte Marsili, Rosetti, and Pasqualucci, 214 USPQ 904 (1972), in which The Board, relying on well established cases of In re Nathan et al., 51 CCPA 1059, 328 F.2d 1005, 140 USPQ 601 (1964); In re Sulkowski, 487 F.2d 920, 180 USPQ 46 (CCPA 1973); Spero v. Ringold, 54 CCPA 1407, 377 F.2d 652, 153 USPQ 726 (1967), and Petisi et al. v. Rennhard et al., 53 CCPA 1452, 363 F. 2d 903, 150 USPQ 669 (1966), concluded that the "products described, exemplified and claimed by Appellants inherently had and have now the structure given in the amendment in question". Applicants are willing to provide the molecular marker profile of PH7JD.

The Examiner states that, "describing a plant that by saying it expresses 2 particular traits does not distinguish it from any other plant that expresses the same traits." Applicants point out that those claims referenced by the Examiner require the utilization of PH7JD to develop such plant. However, in order to expedite prosecution the claims identifying progeny by phenotypic traits have been amended to further define and clearly claim the ancestor of PH7JD expressing all the claimed traits, thereby alleviating the rejection.

The Examiner also states that the morphological and physiological traits of PH7JD progeny are not described. The test of written description does not require a morphological and physiological description. Rather, it is whether subject matter was described in such a way to convey to one of ordinary skill in the art that the inventor had possession of the claimed invention. While PVP is distinct from patents, the scope of protection conferred by PVP provides a clear indication that breeders of ordinary skill in the art consider mutations, F1 hybrids, backcross conversions and transgenic conversions to be within the scope of the invention of the variety itself. See Appendix B. These derivatives, variants and closely related progeny easily and routinely created through the use of this newly developed line are encompassed within the scope of the invention of the variety itself. The fact that the progeny have not been created does not prevent them from being protected in this manner. As stated in MPEP § 2163(3)(a), "An invention may be complete and ready for patenting before it has actually been reduced to practice."

The Examiner also rejects claims 37-39 under 35 U.S.C § 112, first paragraph. Claims 37-39 are directed to growing out an F1 hybrid in which PH7JD is a parent and searching for PH7JD inbred seed. Due to the imperfect process of seed production, parent seed can sometimes be contained in the hybrid seed bag. This claim covers the method of searching for inbred PH7JD seed within a bag of hybrid seed. The method is clearly described in the specification on page 5, line 21 through line 7 on page 6. One of ordinary skill in the art can practice such a method without undue experimentation. The Applicants request that the Examiner withdraw his rejection to claims 37-39.

The Examiner rejects claims to transgenic PH7JD plants and PH7JD plants comprising single gene conversions. New claims 50-73 are drawn to methods and to the products produced by those methods. The product by process claims are further limited by specified traits conferred by mutant genes or transgenes, which include the traits of insect resistance, herbicide resistance, disease resistance, and male sterility.

Applicants respectfully point out that examples of transgenes, mutant genes, genes, and traits that can be introduced into the PH7JD are given in the application on page 21, lines 16-34, and also on page 22, line 34, through page 35, line 25. On page 9 of the Office Action the Examiner suggests that the claims be amended to include a list of transgenes. In order to expedite prosecution new claims 50-73 list the type of traits that

may be conferred. However it should be noted that PH7JD comprising a mutant gene or a transgene, even if it is for a transcription factor, is distinct from another inbred line comprising that same mutant gene or transgene and still retains the benefit of Applicants' invention. Inbred PH7JD stably introgressed to comprise a mutant gene or a transgene is also easily identifiable through the use of molecular markers. The transgenic version of PH7JD would have the same molecular profile as PH7JD, with the possible exception of a marker used in the profile that is located at the site of transgene insertion. However, in this case, the plethora of other identical markers would identify the line as a transgenic variant of PH7JD.

Claims 18-20 and 47-49 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention.

Applicants traverse the rejection. Claims 18-20 have been canceled in order to expedite prosecution. Claims 47-49 have been amended, thereby sufficiently enabling the claims now presented.

In light of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejections to claims 9-20, 28-39, 40-44, 47-79 under 35 U.S.C. § 112, first paragraph.

Issues Under 35 U.S.C. § 102/103

Claims 13, 17, 32, 33, 36, 41, and 43 remain rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Luedtke, Jr. (U.S. Patent No. 6,153,817). The Examiner asserts this rejection is repeated for the reason of record as set forth in the last Office Action mailed July 30, 2002.

Applicants respectfully traverse this rejection. Applicants have canceled claims 17, 32, 33, and 36, thereby alleviating this rejection. Applicants assert the Examiner meant to state claim 14 whereby Applicants have amended claim 14 to particularly claim the specific traits to be expressed by the maize plant, thus alleviating this rejection. Further, Applicants has amended claim 41 that is to the first generation (F1) developed from crossing PH7JD with a second plant. Further claim 43 is a method to the PH7JD-

derived maize plants produced by the method of claim 42. As explained earlier, the hybrid developed from inbred PH7JD as a parent retain the same unique assemblage of genetic material present in duplicate form in the inbred. This contributes predictable traits to the hybrid as described in the specification.

The Examiner states that product-by-process claims may be properly rejected over prior art teaching the same product produced by a different process." It is erroneous to assume that PH0DH is the same as PH7JD either phenotypically or genetically, and Applicants have disclosed information which may be used to distinguish this both from phenotype and genetic profile. PH0DH is not PH7JD, nor can PH0DH be created through the use of PH7JD with one breeding cross. Thus, claim 41 and 43 are not anticipated by PH0DH. Further, Applicants submit In re Thorpe, states that "a product by process claim may be properly rejected over prior art teaching the same product produced by a different process", as noted by the Examiner. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). However, Applicants submit that this is not the same product physiologically or morphologically as the cited prior art as can be evidenced by one skilled in the art through analysis of the data tables in each. In addition, it is impermissible to use hindsight reconstruction and the benefit of Applicants' disclosure to pick among pieces which are present in the art, there must be some suggestion to make the combination and an expectation of success. In re Vaeck, 20 USPQ2d 1434 (Fed. Cir. 1991). Moreover, Applicants claim a method of making a plant which did not previously exist. Pursuant to the recent Federal Circuit decision, Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research, 304 F.3d 1221, (Fed. Cir. 2002), "a novel patented product is not "anticipated" if it did not previously exist." Id. This is the case whether or not the process for making the new product is generally known. Id. The invention PH7JD has not previously existed therefore Applicants strongly assert that neither the suggestion of the claimed unique invention of the present application nor the expectation of success is taught for one ordinarily skilled in the art in the reference cited by the Examiner.

In light of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections to under 35 U.S.C. § 102(e) as anticipated by or, in the

alternative, under 35 U.S.C. §103(a) as obvious over Luedtke, Jr. (U.S. Patent No. 6,153,817).

Summary

Applicants acknowledge that claims 1, 2, 4, 6-8, 21, 23, and 25-27 are allowed.

Conclusion

In conclusion, Applicants submit in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested.

Please charge Deposit Account 26-0084 in the amount of \$410.00 to cover the cost of a two-month extension. Any deficiency or overpayment should be charged or credited to Deposit Account 26-0084. No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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